

**Department of Homeland Security
DHS Directives System
Instruction Number: 248-01-001
Revision Number: 01
Issue Date: 9/10/2012**

MEDICAL QUALITY MANAGEMENT

I. PURPOSE

This Instruction implements Directive 248-01, "Medical Quality Management." It outlines roles and responsibilities in the areas of quality assurance (QA) and performance improvement (PI) to include oversight, credentialing, and risk management (RM) programs.

II. SCOPE

- A. This Instruction applies to all Department of Homeland Security (DHS) Components providing health care services as part of the Component's mission or incidental to its ongoing operations, whether directly, by federal contract, detail, or Inter/Intra-Agency Agreement (IAA).
- B. This Instruction does not apply to:
 - 1. Health care services provided by, for, or on behalf of the United States Coast Guard (USCG) that are in alignment and compliant with Department of Defense, TRICARE, and USCG Commandant Directives and Instructions related to the provision of health care services; or
 - 2. "Lay" medical care or advice that is not in the realm of a licensed professional.

III. REFERENCES

- A. DHS Directive 248-01 "Medical Quality Management"
- B. DHS Delegation 5002 "Delegation to the United States Coast Guard for Privileging Actions"
- C. DHS Delegation 5001 "Delegation to the Assistant Secretary of Health Affairs and Chief Medical Officer"

IV. DEFINITIONS

- A. **Adverse Event:** An occurrence or condition associated with the provision of health care or services that caused harm to the patient. Adverse events may be due to acts of commission or omission.
- B. **Certification/Registration:** The external verification of the competencies that an individual has achieved; typically involves an external process such as the National Registry of Emergency Medical Technicians, National Commission on Certification of Physician Assistants, or a Board recognized by the American Board of Medical Specialties, the American Board of Nursing Specialties, or the American Dental Association.
- C. **Clinical Competency Review:** An active and organized process used by the DHS Components to evaluate and improve care and services. Criteria is clinical in nature and defined by nationally recognized standards of practice and care.
- D. **Clinical Practice Guidelines:** A set of systematically developed statements that should be based on scientific evidence, to assist practitioners and patient decision-making about appropriate healthcare for specific clinical circumstances.
- E. **Credentialing:** The process by which an organization assesses the qualifications and background of professional or para-professional personnel prior to permitting the person to practice designated medical services/skills on behalf of the organization. Such assessment includes, but is not limited to, the primary source verification of professionals' or para-professionals' education, licenses, or certifications/registrations. It does not include the issuing of licenses, certifications, or registrations to professionals and para-professionals for the practice of designated medical health services.
- F. **Emergency Medical Services Training Education Advisory Council (EMSTEAC):** A DHS chartered council that provides advice and recommendations to the Assistant Secretary for Health Affairs/Chief Medical Officer (ASHA/CMO) on matters relating to emergency medical service training and educational policies, regulations, standards, and metrics for EMS personnel.
- G. **Health Care Provider:** An accredited organization, or medically credentialed person, who delivers authorized health care in a systematic way to individuals or groups in need of health care services, including any employees assigned to provide professional or para-professional healthcare services as part of their DHS duties. This also applies to detailees from other federal agencies and contractors whenever the purpose of the detail/contract includes performance of healthcare services.
- H. **Health Care Quality Committee:** A chartered DHS Committee, with representation from all DHS Components and Headquarters offices with equities

relating to healthcare matters, such as the Office for Civil Rights and Civil Liberties, that provides support and advice to the ASHA/CMO on the Medical Quality Management Program (MQM).

I. **Indicator:** A valid and reliable quantitative process or outcome measure related to one or more dimensions of performance, e.g., measuring the performance of a health care provider inserting an intravenous line.

J. **License:** The permission granted to an individual by a State or U.S. Territory or Possession to perform certain medical activities.

K. **Medical Quality Management (MQM) Program:** A program which provides for measurement of system performance and adjustments through training and/or policy to improve quality.

L. **Near-Misses (also known as Close Calls):** An event or situation that could have resulted in harm to the patient but did not, either by chance or through timely intervention. The event was identified and resolved before impacting the patient. An example is a surgical procedure almost performed on the wrong patient but caught before the surgery was initiated.

M. **Peer:** An individual from the same professional discipline/specialty to whom comparative reference is being made.

N. **Peer Review:** The process by which health care providers/professionals evaluate the care of a fellow provider/professional of the same discipline and make determinations about the quality of that care and whether the professional standard of care was met in a given clinical situation.

O. **Performance Improvement (PI):** The continuous study and adaptation of a health care organization's functions and processes to increase the probability of achieving desired outcomes and to better meet the needs of individuals, populations, and other users of services.

P. **Performance Measure:** A measure, such as a standard or indicator, used to assess the performance or process of any organization. A quantitative tool (e.g., rate, ratio, index, percentage) that provides an indication of an organization's performance in relation to a specified process or outcome.

Q. **Preceptor:** A preceptor is an experienced practitioner who, for a set time, teaches, instructs, provides practical experience, training, supervision, and serves as a role model for a provider. Providing preceptorship is a one-to-one clinical experience during which the provider is taught directly by a staff member.

R. **Primary Source Verification:** Verifying a specific credential(s) with the identified institution or entity that provided the credentials (Primary Source) to

determine the accuracy of a qualification reported by an individual health care practitioner.

S. **Quality Assurance (QA):** Systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that nationally recognized standards of care are being met.

T. **Root Cause Analysis (RCA):** A process for identifying the basic or contributing causal factor(s) associated with adverse and/or sentinel events.

U. **Sentinel Event (SE):** An unexpected occurrence during a health care encounter involving patient death or serious physical or psychological injury or illness, not related to the natural course of the patient's illness or condition.

V. **Standard:** Identified level of satisfactory performance applied to a specific indicator that is based on nationally recognized standards and protocols.

W. **Standard of Care:** Health care diagnostic or treatment judgments and actions of a provider/professional generally accepted in the healthcare discipline or specialty involved as reasonable, prudent, and appropriate. Medical standards of care vary: (1) among types of medical facilities such as hospitals, clinics, prehospital emergency medical care and alternate care facilities, (2) based on prevailing circumstances, including during emergencies, and (3) based on the discipline and qualifications of the provider.

V. RESPONSIBILITIES

A. The ASHA/CMO:

1. Has delegated authority to exercise oversight of all medical and public health activities of DHS.
2. Ensures that the MQM Program is appropriately implemented within Components providing health care services and is consistently applied across the department.
3. Approves credentials for all DHS employee health care providers.
4. Establishes credentialing requirements for all DHS contractor and detailee health care providers.

B. DHS Component Heads:

1. Ensure implementation and consistent application of the MQM Program within their Components, to include mechanisms to continually assess and improve performance.

2. Ensure employees, detailees, and contractors have the qualifications and other credentials (licenses, certifications and/or registrations, relevant training and experience) necessary to perform designated medical services before they are permitted to deliver health care services for, or on behalf of, the Department. For contractors, ensure that contracts have specific requirements regarding qualifications and other credentials as noted above. Contracting Officers (CO) and Contracting Officer Technical Representatives (COTR)/ project managers will ensure through contract administration that the contract requirements are met. All requirements for contracts are applicable only for those contracts executed after the effective date of this Instruction.

3. Ensure that contracts and IAAs executed after the effective date of this Instruction include terms and conditions that, if applicable based on the nature of the services being provided: (1) require reporting requirements to the CO, COTR, or Component point of contact (for IAAs), and/or the relevant recognized reporting entities), consistent with this Instruction, for near-miss occurrences, and adverse and sentinel events; (2) require contractors and parties to IAAs to comply with all pertinent requirements of relevant accrediting bodies and the National Detention Standards and/or Performance Based National Detention Standards, consistent with this Instruction; (3) require contractors and parties to IAAs to comply with the recordkeeping requirements in this Instruction; and (4) require contractors and parties to IAAs to provide (to the Component CO, COTR, or POC) the appropriate information needed by the Component to comply with this Instruction, such as providing reports for performance measures, performance improvement, and clinical competency.

4. Establish a process for collecting, tracking, storing, and reporting credentialing documentation.

5. Ensure implementation of Standard Operating Procedures (SOPs) and medical protocols issued by the ASHA/CMO pursuant to this Instruction.

C. Health Care Quality Committee:

A chartered DHS committee, with DHS Component representation that:

1. Identifies performance indicators (feasible for monitoring) which will support the mission, objectives, and strategic plan established by the Office of Health Affairs (OHA) for Components providing health care.
2. Supports all activities of the DHS MQM Program.

3. Promotes continuous quality improvement activities.
4. Keeps abreast of ongoing research and evidence-based practice studies related to prehospital and patient care practices.
5. Recommends actions for training activities to the EMSTEAC and Components for endorsement and action.
6. Provides a report to the ASHA/CMO on all quality assurance and performance improvement activities within the Components for approval
7. Assesses the implementation of ASHA/CMO recommended actions for risk management across the Components.
8. Meets quarterly to perform its responsibilities.

VI. CONTENT & PROCEDURES

A. Clinical Practice Guidelines and Protocols. Components follow established DHS or other recognized and established clinical practice guidelines (CPGs) and protocols in providing health care whether in standing clinics, detention facilities (e.g., CPGs for cardiac, diabetes, asthma from National Commission on Correctional Health Care, Federal Bureau of Prisons, Department of Defense and Department of Veterans Affairs), or other health care settings.

B. Accreditation of Facilities Providing Health Care.

1. Components with DHS facilities providing health care comply with:
 - a. All current requirements of relevant accrediting bodies (such as the American Correctional Association, the National Commission on Correctional Health Care, and the Joint Commission).
 - b. As appropriate, the 2000 National Detention Standards, the 2008 Performance Based National Detention Standards, or the most current adopted detention standards.

C. Quality Framework.

1. DHS Components maintain an active, integrated, organized, and peer/competency based program of quality management and organizational improvement that links peer review, national standards of care, competency assessments, protocols, performance improvement

activities, patient safety, and risk management in an organized systematic way.

2. DHS Components providing healthcare services have a quality assurance, performance improvement, and risk management program in place which focuses on, at the very least:

- a. Performance Measures
- b. Performance Improvement
- c. Clinical Competency
- d. Risk Management & Assessment
- e. Records Management
- f. Credentialing
- g. Standard Operating Procedures and Protocols

D. Performance Measures.

In focusing on performance measures, Components develop measurable indicators that can be systematically tracked to assess progress in achieving goals, and improving performance. Performance Measures are:

1. Related to the quality and delivery of care;
2. Relevant to the specific mission and/or of interest in value;
3. Oriented to structure, process, and outcome;
4. Based upon evidence, especially that related to clinical issues;
5. Clearly linked to outcome by structure or process;
6. Reliable, valid, and feasible; and
7. Continually evaluated for relevance.

E. Performance Improvement

1. For performance improvement, Components develop a performance improvement program that supports identification of a concern or area for improvement. In doing so, Components may evaluate

the Component's performance against nationally recognized patient care standards and outcome measures; industry and national benchmarks; data collection; and re-evaluation of progress aligned to performance measurement.

2. Any monitoring and evaluation of data for performance improvement purposes is reliable, valid, and ongoing.
3. Components engage in at least one performance improvement activity per year and in more than one performance improvement activity if the Health Care Quality Committee provides advice to Components to engage in additional performance improvement activities.
4. The performance improvement program utilizes the problem-solving model, or equivalent, found below:

FOCUS-PDCA:

F - Find a process to improve	P - Plan the improvement
O - Organize a team that knows the process	D - Do the improvement (pilot, process, test)
C - Clarify current knowledge of the process	C - Check the results of the improvement
U - Understand the cause or variations	A - Act
S - Select the process improvement	

5. Components report the results of their performance improvement activities to the OHA MQM mailbox (ohamqm@hq.dhs.gov) annually.

F. Clinical Competency.

1. Components perform clinical competency reviews at least twice per year.
2. Components base competency reviews on criteria that are defined by the ASHA/CMO through guidance and by criteria established by the Component.
3. Criteria established by the Component is clinical and defined by nationally recognized standards and/or the health care provider's scope of practice.
4. Competency reviews are performed by a peer of the health care provider or by a preceptor.
5. Competency reviews may vary for each Component based on specific mission areas. In addition to the requirements set forth above, competency reviews will, if practicable, include consideration of patient records (e.g., a record review to determine appropriateness of

documentation; disease management; age-appropriate treatment and preventive care; outcome review; continuum of care review; procedures performed; and protocol management).

6. Components are encouraged to focus on low-volume or high-risk areas as appropriate, and use evidence-based criteria with available nationally recognized benchmark standards or thresholds.

G. Risk Management & Assessment.

1. Components establish an internal review process for near-miss occurrences, adverse events, and sentinel events. Component heads designate a medical professional in the Component to establish the internal review process.

2. Near-miss Occurrences.

a. Components establish a process for the review of near-miss occurrences in federal facilities (e.g., those incidents requiring incident reports).

b. Each near-miss occurrence in a federal facility is reviewed by a federal employee (DHS or non-DHS). If there is not a federal health care provider in the Component who may conduct the review, Components contact OHA for assistance in locating a federal health care provider to conduct the review. The recommended reviewer, if from OHA, is not involved in any determinations and recommendations by the ASHA/CMO regarding the quality of health care of the Component health care system as it related to the specific instance.

c. Components recommend corrective actions, including timelines, for each near-miss occurrence, as appropriate, adjusting and correcting any system or process problems that contributed to the near-miss.

d. The health care provider(s) involved in the near-miss occurrence has an opportunity to provide a written statement to the Component regarding the near-miss occurrence. The written statement is included in any compilation of information by the Component or in any report the Component makes to the ASHA/CMO regarding the specific near-miss occurrence. Components provide health care providers at least **15 business days** notice of the time to submit the written statement.

e. Components submit a report of near-miss occurrences quarterly, with recommended corrective actions, to the ASHA/CMO via the OHA MOM mailbox

(b)(6),(b)(7)(C)

f. The review is conducted based upon nationally recognized standards of care and practice.

g. Components report near-miss occurrences by federal employees in accordance with recognized reporting practices and to recognized reporting entities, when appropriate. Components may choose to ask OHA for assistance in reporting near-miss occurrences if Components do not have a structure in place to report near-miss occurrences. For near-miss occurrences by contractors and others under service agreements with DHS, Components follow the reporting mechanisms identified within the applicable contracts and agreements, which may vary based on the place (e.g., state or territory) where the near-miss occurred or the health care provider's state license.

h. In accordance with applicable federal law, Components take adverse or disciplinary action(s), as appropriate, regarding DHS employees. For detailees, Components address any adverse or disciplinary action(s) in accordance with the terms of applicable agreements with the federal department or agency from which the federal employee is detailed.

3. Adverse and Sentinel Events.

a. Components review every adverse and sentinel event that occurs in DHS facilities, on DHS property, or during field operations.

b. Components notify OHA of every sentinel event that occurs in DHS facilities, on DHS property, or during field operations, that results in a death within 48 hours of the sentinel event.

c. Each review of adverse and sentinel events contains a Root Cause Analysis (RCA).

i. For an RCA to be effective, the steps outlined in the Framework for a Root Cause Analysis and Action Plan in Response to a Sentinel Event (Attachment 1) are completed.

ii. For the RCA, Components identify a team of those familiar with the event as well as subject matter experts (as

appropriate) to conduct a thorough review of all relevant medical records and supportive documents. The team consists of qualified medical federal employees (DHS or non-DHS). If there are insufficient federal health care providers in the Component who may conduct the RCA, Components contact OHA for assistance in locating federal health care providers to conduct the RCA. The recommended reviewers, if from OHA, are not involved in any determinations and recommendations by the ASHA/CMO regarding the quality of health care provided by the Component health care system as it relates to the specific instance.

iii. The RCA is completed within **45 business days** of the incident. If additional time is required, a formal written request by the Components to the ASHA/CMO is submitted. The request includes the reason for the requested extension and estimated date of completion of the RCA. No further extensions are granted thereafter.

d. Adverse and sentinel event reviews also consist of an assessment of whether the standard of care was met in relation to nationally recognized standards of care and practice for the particular type of adverse and sentinel event. This includes a review of all relevant medical records, including interviews, as appropriate. This assessment is conducted, at the very least, by a peer who is from the same professional discipline/specialty as the individual undergoing review. If there is no peer available for the assessment within the Component, the Component contacts OHA for assistance in locating a peer. The recommended peer, if from OHA, is not involved in any decisions by the ASHA/CMO regarding the quality of health care provided by the Component health care system in that specific instance. Peers are credentialed as DHS health care providers.

e. Components compile a report on each adverse and sentinel event and submit the report to the ASHA/CMO for review within **45 days** of the adverse and/or sentinel event. This report includes the RCA, findings, recommended actions with timetable for improvements, and all relevant supporting medical and investigation documents. Components submit copies of medical documents and retain originals. The Component sends the report to OHA via a password-protected email to the OHA MQM mailbox (OHAMedicalQualityManagement@dhs.gov). Components identify a POC in the email to OHA.

f. If the submission of reports and required documents is unduly delayed or delinquent, the ASHA/CMO notifies the Component Head through a formalized letter. All delayed submissions are noted in OHA's quarterly report to the Secretary.

g. The health care provider(s) involved in the adverse and/or sentinel event will have an opportunity to provide a written statement to the Component regarding the event. The written statement is included in any compilation of information by the Component or in any report the Component makes to the ASHA/CMO regarding the adverse and/or sentinel event. Components provide health care providers at least **15 business days** notice of the time to submit the written statement.

h. Components report adverse and sentinel events involving federal employees in accordance with recognized reporting practices and to recognized reporting entities, when appropriate. For adverse and sentinel events involving contractors or health care providers under service agreements, Components follow the reporting mechanisms identified within the applicable contracts or service agreements, which may vary based on the place (e.g., state or territory) where the health care provider involved in the adverse and sentinel event has a license.

i. In accordance with federal law, Components take adverse or disciplinary actions, as appropriate, regarding DHS employees. For detailees, Components address any adverse or disciplinary actions in accordance with the terms of applicable agreements with the federal department or agency from which the federal employee is detailed.

H. Provision of Notice to the Office of Inspector General (OIG) and Component's Internal Investigatory Office.

Components provide notice of sentinel events to the OIG and, if required by internal Component policy, the Component's internal investigatory office (e.g., the U.S. Immigration and Custom Enforcement's Office of Detention Oversight, Office of Professional Responsibility) within **48 hours** of a sentinel event.

I. Office of Inspector General and Component Internal Investigatory Office Reports.

If the OIG and/or the Component's Internal Investigatory Office determine to initiate an investigation and generate a report on a particular sentinel event, the OIG or Component's internal investigatory office notifies OHA of this decision as soon as possible. The OIG or Component's internal investigatory office provides

a report of its findings to OHA as soon as completed, if permissible and appropriate. It is OHA's goal to receive the report within **60 business days**, so that OHA may take any necessary actions in a timely manner. The OIG and/or the Component's Internal Investigatory Office may forward the report to OHA via a password-protected email to the OHA MQM mailbox (OHAMedicalQualityMangagement@dhs.gov), identifying a POC in the email to OHA.

J. OHA Review of Adverse and Sentinel Events.

1. After the Component and/or the OIG or Component Internal Investigatory Office submit reports of adverse and sentinel events to the ASHA/CMO, a medical professional under the authority of the ASHA/CMO, with credentials appropriate for reviewing medical records, conducts a review of the adverse and sentinel events reports. The scope of the review is to determine whether the Component followed the applicable standards of care and recommend processes for improvement, if warranted.
2. If the reviewing medical professional (reviewer) finds that there are no inconsistencies in the collected reports, the reviewer submits to the ASHA/CMO a conclusion as to whether the Component followed the applicable standards and provides initial recommended and/or corrective actions the Component should take regarding the adverse or sentinel event. The ASHA/CMO, based on the reviewer's initial conclusions and recommended and/or corrective actions, as well as the accompanying medical reports, develops a final report of conclusions, recommendations, and/or corrective actions, which is submitted to the Component.
3. If the reviewer finds that the reports are inadequate, incomplete, or inconsistent with one another, the reviewer informs the Component and/or OIG or Component Internal Investigatory Office of the noted inadequacies, incompleteness, or inconsistencies and requests that the Component and/or OIG or Component Internal Investigatory Office address the identified inadequacies, incompleteness, or inconsistencies in a revised report within **15 business days** of the request.
4. The reviewer submits to the ASHA/CMO a conclusion as to whether the Component followed the applicable standards and provides initial recommended and/or corrective actions the Component should take regarding the adverse or sentinel event. If the reviewer finds that inadequacies, incompleteness, or inconsistencies remain in the report(s) even after revisions, the reviewer also details the inadequacies, incompleteness, or inconsistencies.

5. The ASHA/CMO develops a final report, with conclusions, recommendations, and/or corrective actions, based on the ASHA/CMO's medical judgment.

a. The ASHA/CMO may, at his/her discretion, convene an expert panel of federal personnel with medical or other relevant expertise (from within DHS or from outside DHS) via appropriate details, memoranda of agreement/understanding, or Inter-agency Agreements to review the submitted reports and accompanying documents and determine whether information collected from the report(s) supports the conclusions initially reported, whether the Component followed the applicable standards of care, and recommended and/or corrective actions. The expert panel submits a written report to the ASHA/CMO and details any inadequacies, incompleteness, or inconsistencies in submitted reports that were noted.

b. After a review of the expert panel's report, the ASHA/CMO either rejects or accepts the report's conclusions, recommendations, and/or corrective actions. If the ASHA/CMO accepts the expert panel's report without change, the ASHA/CMO develops a final report, which is submitted to the Component. If the ASHA/CMO rejects the expert panel's conclusions, recommendations and/or corrective actions, the ASHA/CMO convenes the expert panel for discussion of the ASHA/CMO's concerns with the report and the expert panel may choose to revise its conclusions, recommendations and/or corrective actions. If the ASHA/CMO remains dissatisfied with the expert panel's conclusions, recommendations and/or corrective actions, the ASHA/CMO may choose to make a final rejection of the panel's report and issue a final report, with conclusions, recommendations and/or corrective actions, based on the ASHA/CMO's medical judgment.

K. Status Reports

1. Components provide a bi-annual report (every six months) to OHA regarding the Component's progress in implementing the ASHA/CMO recommendations or corrective actions for each reported and reviewed adverse and sentinel event (including whether no corrective action was taken or whether actions were taken and the matter is closed).

2. The ASHA/CMO provides a quarterly report to the Secretary outlining the status of all adverse and sentinel event reviews, including those reviews open, closed, and delayed by the failure of Components to submit reports or required documentation within the timeframe specified in

this Instruction. The report also includes the status of Components' implementation of recommendations and corrective actions.

L. Litigation/Claims

1. If a claim or allegation against DHS or a Component(s) is made regarding improper or substandard health care, the affected Component notifies OHA and OGC of this claim or allegation within **48 hours** of receiving notification or knowledge of the claim or allegation. Original medical records, regardless of medium, are secured to ensure against loss or alteration. Patients may be treated, and Quality Assurance reviews conducted, utilizing copies of the records.

2. If the claim or allegation involves a near-miss occurrence, the Component develops and submits a report to OHA via a password-protected email to the OHA MQM mailbox

(b)(6),(b)(7)(C)

including any written statement by the health care provider, within **45 days** of receipt of the claim or notification of the allegation.

3. For claims or allegations involving an adverse or sentinel event, the Component commences the procedures outlined in this Instruction with respect to adverse and/or sentinel events.

4. OHA and the Department's findings with respect to the Component's standard of care are independent of findings made by a court or administrative body or tribunal with jurisdiction over the claim or litigation. Any findings, judgments, or settlements made by a court or administrative body or tribunal do not affect the ASHA/CMO's final determinations or reports. The ASHA/CMO does not, in response to findings made by a court or administrative body or tribunal, conduct a second review of near-miss occurrences, adverse or sentinel events after the ASHA/CMO has made a final report.

M. Record Handling.

1. Components maintain medical records and reports (paper and/or electronic) following the same standards the Components utilize for protecting other confidential records or information containing personally identifiable information. Components ensure that all Privacy Act and other applicable recordkeeping requirements are fulfilled. As indicated above, medical records which are evidence in a claim or litigation are secured, so that access to the original records is extremely limited.

2. OHA manages and maintains reports and supporting documents (paper and/or electronic) in a secure location and ensures that all Privacy Act and other applicable recordkeeping requirements are met.

3. Once the review is complete, OHA returns copies of all relevant medical documents to the DHS Component Head or delegate.

N. Licensure, Certification, and/or Registration of Health Care Personnel.

1. Health care providers maintain a license, certification, and/or registration (issued by a national registration body) that is current, active, valid, and, in the case of physicians, unrestricted. For health care providers who are not physicians, any license, certification, and/or registration may be restricted and/or unrestricted with respect to the scope of activities the health care provider may perform and the location where health care providers may provide medical services.

2. Persons credentialed to provide health care services on behalf of DHS pass a nationally recognized certification exam or state-recognized certification exam (or equivalent) approved by the ASHA/CMO and are certified by the national or state institution. Emergency Medical Technicians (EMTs) meet the appropriate level of National Registry of Emergency Medical Technicians (NREMT) certification, and Registered Nurses (RN) are state licensed. The ASHA/CMO annually provides Components with a list of nationally recognized certification exams that the ASHA/CMO considers acceptable for credentialing purposes. For state-recognized certification exams, the ASHA/CMO determines, on a case-by-case basis, whether the state-recognized certification exams are acceptable. If the health care provider has an option between taking a nationally recognized certification exam and a state-recognized certification exam, health care providers take the nationally recognized certification exam or equivalent.

3. For Physicians, examination includes all components of the National Board of Medical Examiners certification examination, the Federal Licensing Examination (FLEX) for graduates of foreign medical schools, or the United States Medical Licensure Examination (USMLE). Under certain circumstances, various combinations of these examinations may be acceptable, but this is approved on a case-by-case basis by the ASHA/CMO.

4. Physician Assistants (PA) have current and valid state licenses and are validated by the National Commission on the Certification of Physicians Assistants (NCCPA).

5. Components monitor the status of individual professional licensure, certification, and/or national registration for all health care providers. DHS health care providers are responsible for maintaining their required continuing education and licensing, certification, or registration requirements and for updating their supervisors on the completion of specified, required continuing education and licensing, certification, or registration requirements. DHS health care providers input and update their continuing education training in the appropriate DHS databases (e.g., the Learning Management System), when possible.

6. OHA provides oversight and works directly with the Components to identify any licensure, credentialing, and/or national registration concerns, and provides guidance on resolution, whether in response to a request for credentialing, or in general.

O. Credentialing Process.

1. Requests for credentialing of a current DHS employee may be made by either the DHS employee or the Component. Components should endeavor to include the DHS employee in the request for credentialing process and work with the DHS employee in locating and submitting the necessary supporting documentation.

2. The required documentation includes qualification data such as relevant training and experience, current licensure, specialty certification (if applicable), as well as performance data such as current skills competency. This data is collected, verified, and assessed initially and reviewed periodically. Credentialing packages include:

a. A cover letter requesting consideration for credentials, including a brief overview of the mission that the individual is to perform, scope of practice, and qualifications.

b. A listing of qualifying degrees, diplomas, post-graduate training, licensure information, board certifications (if applicable), other certifications (if applicable), and formal training (if applicable).

c. Any additional information regarding the DHS employee's competencies and performance of health care services on behalf of DHS.

3. Components submit credentialing package(s) electronically to the OHA Credentials mailbox (b)(6),(b)(7)(C) to be processed.

4. Licenses, certifications, and/or registrations are verified with the state licensing boards, or other state certifying or national registry bodies for Physicians, Nurses, Physician's Assistants, and Emergency Medical Services Providers.
5. Failure of an Applicant to Meet Qualifications – Initial Determination
 - a. The Credentials Reviewer must be a physician who reports directly to the ASHA/CMO. During the initial review, if the OHA medical professional assigned to review and evaluate credentials determines that the applicant fails to meet the qualifications and credentials verification; the Credentials Reviewer provides written notice to the requesting Component that the applicant's package was not approved and the reasons underlying the decision. .
 - b. The Component may, within **15 business days** after receiving the written notice of disapproval, resubmit an updated credentialing request for the applicant, along with any additional supporting documentation for the Credentials Reviewer's consideration. If the Component determines more time is required to submit an updated credentialing request, the Component notifies the Credentials Reviewer of this determination and provides an estimated time frame when the Component may submit the updated request. The Component and Credentials Reviewer will determine an agreed-upon date for resubmission of the credentialing request. No further requests for extension are granted thereafter.
 - c. The Credentials Reviewer provides a recommendation to the ASHA/CMO and the ASHA/CMO, within **15 business days after the time period for resubmission of credentialing requests or agreed-upon extension**, makes a final determination with respect to whether the applicant meets the qualifications, and notifies the Component of this determination in writing. If the ASHA/CMO requires additional time to reach a final determination, OHA will provide notice to the Component within the aforementioned 15 business days.
6. Failure of a DHS Employee to Meet Qualifications – Preliminary Determination
 - a. If, upon review of the written request and supporting documents of a DHS employee, the Credentials Reviewer determines that the DHS employee fails to meet the qualifications, the Credentials Reviewer provides a written notice to the requesting Component and the DHS employee that the Credentials Reviewer

has made a preliminary determination that the DHS employee's credentials do not meet the qualifications, the reasons underlying the decision, and that the employee should be de-credentialed or not be awarded credentials.

b. The Component and DHS employee, separately or together, may submit a written response, including additional documentation, to the OHA Credentials mailbox (b)(6),(b)(7)(C) in response to the Credentials Reviewer's preliminary determination. The Component and DHS employee shall make reasonable efforts to submit a written response within **15 business days** of receiving the Credentials Reviewer's preliminary determination. If the Component determines more time is required to submit an updated credentialing request, the Component notifies the Credentials Reviewer of this determination and of an estimated time frame when the Component may submit the updated request. The Component and Credentials Reviewer determine an agreed-upon date for resubmission of the credentialing request. No further requests for extension are granted.

7. Final Determination and Notice of Appeal

a. If the Component or DHS employee does not submit a written response to the Credentials Reviewer within **15 business days** of the Credentials Reviewer's preliminary determination or other agreed-upon time frame or date, the ASHA/CMO provides a final, written determination that the DHS employee does not meet the qualifications, i.e., that the employee is de-credentialed or has not been awarded credentials.

b. If the Component or DHS employee submits a written response to the Credentials Reviewer within **15 business days** of the Credentials Reviewer's preliminary determination or other agreed-upon time frame or date, the Credentials Reviewer makes a reasonable effort within **15 business days** of receiving the response, to review the response and provide a preliminary final written determination to the ASHA/CMO on whether the DHS employee meets the credentialing qualifications. The ASHA/CMO makes a final written determination as to whether an employee meets credentialing qualifications.

c. If the ASHA/CMO makes a final, written determination that the DHS employee meets the qualifications, the ASHA/CMO provides a final, written determination to the relevant Component and DHS employee or detailee, notifying the Component and employee or detailee that he/she is credentialed.

d. If the ASHA/CMO provides a final, written determination that the DHS employee does not meet the qualifications and will be de-credentialed or not awarded credentials, the ASHA/CMO's final, written determination informs the Component and employee of the reasons for the de-credentialed determination and provides for an availability of the documents relied upon in the de-credentialed determination for the employee's review, upon request.

e. The DHS employee or detailee may request reconsideration of an unfavorable final, written determination of the ASHA/CMO within **45 business days** of receiving the ASHA/CMO's final written determination. The request for reconsideration is submitted to the OHA Credentials mailbox (b)(6),(b)(7)(C) in writing, to the attention of the ASHA/CMO and provides a response to the ASHA/CMO's final written determination as well as any supporting documentation that would aid in the ASHA/CMO's review of the DHS employee's request for reconsideration.

f. The ASHA/CMO makes a reasonable effort to, within **45 business days** of receiving a written appeal, issue a final determination to the employee and to the Component. If the employee is not credentialed, or de-credentialed, the employee is notified of the reasons for the determination and, upon the employee's request, provided access to any materials underlying the determination.

8. In accordance with applicable federal law, Components take adverse or disciplinary action(s), as appropriate, regarding DHS employees, and relating to de-credentialed. For detailees, Components address de-credentialed in accordance with the terms of applicable agreements with the federal department or agency from which the federal employee is detailed.

P. Centralized Credentials Management System.

1. OHA, Workforce Health and Medical Support Division, keeps a record of all relevant documentation concerning the DHS employee's or applicant's credentials for a period of time pursuant to the applicable General Records Schedule: OPM/GOVT-1, General Personnel Records and General Records Schedule 1, Official Personnel Folder.

2. Credentialing information is stored in a locked file cabinet and/or in a secure database that is password protected. The ASHA/CMO assigns an OHA medical professional to manage the collected or uploaded credentialing records ("Credentials Manager"). DHS Components protect

confidential credentialing records following the same standards the Components utilize for protecting other confidential records or information containing personally identifiable information.

Q. Standard Operating Procedures and Protocols.

1. The ASHA/CMO, or his/her authorized designee, periodically and as necessary, issues Standard Operating Procedures (SOPs) and medical protocols to provide guidance to Components on the provision of medical care on behalf of DHS.
2. The SOPs and medical protocols address the provision of medical treatment during daily operations and activities, ranging from SOPs and protocols related to the provision of medical treatment in DHS facilities and the administration/dispensation of medicine to SOPs and protocols related to the provision of medical care in remote and/or medically austere environments and during or in response to a catastrophic incident, major disaster, or emergency.
3. Components adhere to SOPs and medical protocols as the SOPs and protocols relate to Components' missions and activities and consult with OHA if the Component has questions or concerns with respect to the applicability of an SOP or medical protocol to a Component's mission or activities.
4. This is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

QUESTIONS

Direct questions or issues related to this document to OHA, Workforce Health and Medical Support Division, or to (b)(6);(b)(7)(C)

(b)(6);(b)(7)(C)

— 9/10/12
Date